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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/755,424	01/05/2001	Donald S. Guzik	1416.33US01	4784
27367	7590	09/20/2005	EXAMINER	
WESTMAN CHAMPLIN & KELLY, P.A. SUITE 1400 - INTERNATIONAL CENTRE 900 SECOND AVENUE SOUTH MINNEAPOLIS, MN 55402-3319			JOHNSON, JONATHAN J	
			ART UNIT	PAPER NUMBER
			1725	

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/755,424

Applicant(s)

GUZIK, DONALD S.

Examiner

Jonathan Johnson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8-3-05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 2-5,9,13-45,47 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-8,10-12,46 and 49-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6-8, 10-12, 46, and 49-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen (6,528,006) in view of Yamane et al. (5,875,004). With respect to Claims 1, 46, and 50-51, Jansen teaches a method for producing a prosthesis having at least partially cutting a material segment with a beam (abstract) where the target is a pericardial patch and chordae (col. 4, ll. 15-65 and col. 1, ll. 10-55), where the laser is programmed to cut only to a particular depth (col. 2, ll. 20-40). Yamane et al. teach a process control unit to compare the workpiece to correspond to a target image (Yumane et al.; Column 2, lines 40 through Column 4, Line 25). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Jansen in order to utilize a process control method in order to automatically execute a visual inspection along the entire surface containing multiple points(Yumane et al.; column 1, lines 10-20).

With respect to Claim 6, the teachings of Jansen and Yamane et al. are the same as relied upon in the rejection of Claim 1. Jansen teaches the target image has a leaflet section (Column 1, Lines 10-20).

With respect to Claim 7, the teachings of Jansen and Yamane et al. are the same as relied upon in the rejection of Claim 1. Yamane et al. teach the target image is determined by a) forming a digital image of the material segment (Column 5, Lines 59-60); b) comparing the digital image to a target image to evaluate the difference between the digital image and the target image (Column 5, Lines 60-65); and c) determining a cutting pattern based on the difference (Column 6, lines 5-18). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Jansen in order to utilize a process control method in order to automatically execute a visual inspection (Yamane et al.; column 1, lines 10-20).

With respect to Claim 8, the teachings of Jansen and Yamane et al. are the same as relied upon in the rejection of Claim 7. Yamane et al. teach the digital image is formed using a video camera (Column 5, Lines 60 through Column 6, lines 17). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Jansen in order to utilize a video camera in order to automatically execute a visual inspection (Yamane et al.; column 1, lines 10-20).

With respect to Claim 10, the teachings of Jansen and Yamane et al. are the same as relied upon in the rejection of Claim 7. Yamane et al. teach the cutting pattern involves forming the cutting pattern based on the border between the digital image and the target image (Column 6, Lines 5-17). It would have been obvious to one of ordinary skill in the art at the time of the

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invention to modify the method of Jansen in order to utilize a process control method in order to automatically execute a visual inspection (Yamane et al.; column 1, lines 10-20).

With respect to Claim 11, the teachings of Jansen and Yamane et al. are the same as relied upon in the rejection of Claim 7. Yamane et al. teach the cutting pattern is selected to avoid cutting any material that forms a portion of the target object (Yamane et al; column 6, Lines 5-19). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Jansen in order to utilize a process control method in order to automatically execute a visual inspection (Yamane et al.; column 1, lines 10-20).

With respect to Claim 12, the teachings of Jansen and Yamane et al. are the same as relied upon in the rejection of Claim 7. Yamane et al. teach orienting the digital image relative to the target image prior to comparing the digital image with the target image (Yamane et al.; column 5, line 55 through column 6, Line 20).

With respect to Claims 49 and 52-60, Jansen teaches cutting the tissue sheet to separate portions of the tissue sheet with a thickness outside of a selected range; wherein the imaging is performed with a laser (abstract and Column 1, lines 14-20); where the cutting is controlled by a process control unit (col. 4, ll. 40-50); wherein the target image is a leaflet section or pericardial patch or chordae (col. 4, ll. 15-45 and col. 1, ll. 10-55). Yamane et al. teach the cutting is controlled by a process control unit to cut the material to correspond to a target image; wherein the selected range is provided by a target image; wherein the tissue sheet produces a digital

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image, which is oriented proper direction. (Yumane et al.; Column 2, lines 40 through Column 4, Line 25). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Jansen in order to utilize a process control method in order to automatically execute a visual inspection (Yumane et al.; column 1, lines 10-20).

Response to Arguments

Applicants "do not understand what the new ground(s) of rejection are." In the second action non-final office action mailed on 3-1-05, the examiner changed the statement of rejection (to include claim 46) as well as portions in the body of the rejection.

Applicants argue the prior art does not teach the claim 1 limitation "cutting is controlled by an automated process unit" because neither Jansen or Yamane teach a feedback control system. The examiner disagrees. Jansen teaches (col. 2, ll. 19-22 and col. 2, l. 44) using a laser to form a predetermined contour at a predetermined thickness. In addition, Jansen teaches (col. 2, ll. 46-51) scanning the instantaneous thickness and storing them to generate setting parameters (e.g., energy density, pulse rate, and effective duration). Jansen, however, does not teach a control system. Yamane teaches a control system capable of handling this process. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Jansen in order to utilize a process control method in order to automatically execute a visual inspection along the entire surface containing multiple points (Yumane et al.; column 1, lines 10-20).

Applicants argue the prior art does not teach the claim 46 limitation of "cutting a tissue sheet to remove portions of the tissue sheet having different thicknesses." The examiner

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disagrees. Jansen teaches this limitation when he teaches producing a film with a predetermined contour and thickness by a separation and/or ablation machining method (see col. 1, ll. 14-20).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

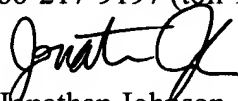
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan Johnson whose telephone number is 571-272-1177.

The examiner can normally be reached on M-Th 7:30 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom Dunn can be reached on 571-272-1171. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jonathan Johnson
Primary Examiner
Art Unit 1725